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| 09/912,494 | 07/24/2001 | Theodore M. Wong | SP-1093.2 | 7897 |

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Richard B. Taylor
Protein Technologies International, Inc.
P.O. Box 88940
St. Louis, MO 63188

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|------------------------------------|--|
| Notification of Non-Compliant Appeal Brief (37 CFR 41.37) | Application No. 09/912,494 | Applicant(s) WONG ET AL. | |
| | Examiner Deborah K. Ware | Art Unit 1651 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on 26 March 2004 is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file an amended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer.
EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.
2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).
3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).
4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).
5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi)).
6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).
7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).
8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).
9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).
10. ☒ Other (including any explanation in support of the above items):

Furthermore, although the brief was filed March 26, 2004, before a board decision was rendered on May 4, 2004 in related case serial no. 09/785,936 which was a continuation of instant application's parent case serial no. 08/996,976, Applicants are urged to include in their amended brief a copy of the decision attached hereto. Applicants should also be aware that there is a separate heading section required for decisions under 37 CFR 41.37c(1)(x)-Related Proceedings Appendix. Applicants should note that any evidence in their appendices in instant case are not under the proper heading 41.37c(1)(ix)-Evidence Appendix. Further, the appealed claims should be submitted under their own heading in accordance with 41.37(c)(viii)-Claims Appendix. An amended brief in accordance with 37 CFR 41.37(d) will better present this Application for appeal.


DEBORAH K. WARE
PATENT EXAMINER

Delbert K. Ware
DEBORAH K. WARE
PATENT EXAMINER

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 19

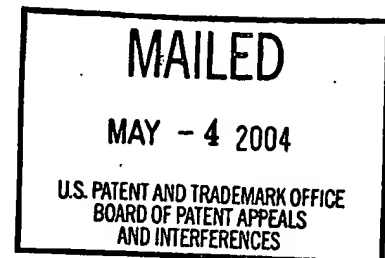
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THEODORE M. WONG,
DAVID A. SINGER, and
SANTA H. LIN

Appeal No. 2004-0450
Application No. 09/785,936

ON BRIEF



Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 79 through 94, 97 through 111, 113 through 118, and 120 through 129, which are all of the claims remaining in this application. The claims have been grouped together (Appeal Brief, page 4). Accordingly, for the purposes of this appeal, we shall treat all claims as standing or falling with representative claim 79:

79. A method for producing a purified vegetable protein material having low concentrations of ribonucleic acids, phytic acid, and phytates, comprising:

forming an aqueous slurry of a vegetable protein material and an enzyme preparation containing an acid phosphatase enzyme and a phytase enzyme, wherein said enzyme preparation is present in said slurry in an amount relative to the protein material of from about 0.1% to about 10% by weight of the protein material (dry);

treating the slurry containing the protein material and the enzyme preparation at a temperature, a pH, and for a time period effective to enable said acid phosphatase enzyme to degrade ribonucleic acids in the vegetable protein material and to enable said phytase to degrade phytic acid and phytates in the vegetable protein material; and

washing the vegetable protein material after treatment to degrade ribonucleic acids, phytic acid, and phytates to provide a vegetable protein material having reduced concentrations of ribonucleic acids, phytic acid, and phytates.

In rejecting applicants' claims on prior art grounds, the examiner relies on the following reference:

European Patent Application

0 380 343 A2

Aug. 1, 1990

All of the appealed claims stand rejected under 35 U.S.C. § 102 or § 103 as unpatentable over European Patent Application 0 380 343 A2 ('343 patent). We shall affirm this rejection.

PROCEDURE

To dispel ambiguity, we shall first clarify what evidence is of record. On June 17, 2003, applicants filed a Reply Brief (Paper No. 16) with three exhibits attached: a BASF

publication describing the phytase Natuphos® (Exhibit A); the Wong declaration (Exhibit B); and the Taylor declaration (Exhibit C).

As stated in 37 CFR § 1.195,

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

The examiner, however, did not invoke that rule to deny entry of Exhibits A, B, or C, despite the absence of "a showing of good and sufficient reasons why they were not earlier presented." Rather, in the Office communication mailed September 11, 2003 (Paper No. 17), the examiner stated that "[t]he reply brief filed June 17, 2003 has been entered and considered." In our judgment, the only plausible interpretation which these facts permit is that the examiner considered and made of record Exhibits A, B, and C. This follows because, in their Reply Brief, applicants set forth arguments based on those exhibits, and the examiner entered and considered the Reply Brief.

Additionally, applicants' main Brief (Paper No. 14), received January 29, 2003, includes Appendix C and Appendix D. The former was filed before the Final Rejection in this application and is clearly of record. The latter was filed with the main Brief. Again, however, the examiner did not invoke the provisions of 37 CFR § 1.195 to deny entry of Appendix D. On contrary, the examiner has considered and discussed Appendix D in the Answer, page 13, first full paragraph. It is apparent, therefore, that Appendix D has been entered and made of record.

THE MERITS

Claims 79 through 94, 97 through 111, 113 through 118, and 120 through 129 stand rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over the '343 patent. This reference discloses a method for producing a phytate-free or low phytate soy protein isolate and concentrate using one or more phytate-degrading enzymes. The '343 patent discloses phytate-degrading enzymes which include phytases and acid phosphatases. "Particularly preferred for the purposes of the present invention are the Finase enzymes" ('343 patent, page 6, line 26). It is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase.¹

The examiner's main argument is that, although the prior art does not explicitly disclose the degradation of RNA, a person having ordinary skill in the art, armed with the disclosure of the '343 patent and carrying out its method using the preferred enzyme, Finase, would inevitably and necessarily degrade RNA present in the soy protein.²

¹ "A combination of phytase and a pH 2.5 optimum acid phosphatase form A. niger has been used by Alko, Ltd. as an animal feed supplement in their phytic acid degradative product Finas [sic] F and Finase S." U.S. Patent No. 6,190,897 issued February 20, 2001, to Kretz, column 2, lines 18 through 22 (copy enclosed with this opinion).

² See the Final Rejection (Paper No. 9, page 3), "the degradation of RNA is inherent to the enzyme digestion of the vegetable protein as disclosed by the cited reference;" and see the Examiner's Answer (Paper No. 15, page 5), "RNAs are inherently degraded by the acid phosphatase present in the Finase enzyme of the cited disclosure."

According to applicants, claim 79 is not anticipated by the cited prior art because:

[T]he '343 patent does not disclose 1) the degradation of ribonucleic acids; 2) where the ribonucleic acid degradation is effected with an acid phosphatase enzyme; or 3) the formation of an aqueous slurry or mixture of vegetable protein material and an acid phosphatase enzyme or an enzyme preparation containing an acid phosphatase enzyme, where the acid phosphatase enzyme or enzyme preparation is present in the slurry or mixture in an amount of from about 0.1% to about 10% by weight of protein material (dry). [Appeal Brief, page 6]

RNA Degradation

The '343 patent does not explicitly mention RNA or the degradation of RNA.

Nonetheless, applicants acknowledge that

Commercially available protein concentrates and isolates . . . contain some impurities which are undesirable in products such as infant formulas. Specific impurities which are undesirable in vegetable protein isolates and concentrates include phytic acid, phytates, ribonucleic acids, ash, and minerals bound to phytic acid, phytates, or ribonucleic acids which are unavailable for human assimilation such as phosphorus, calcium, chloride, iron, zinc, and copper. It is desirable to provide methods for reducing the levels of these impurities in vegetable protein isolates and concentrates, particularly for use in products such as infant formulas. [Specification, page 1, lines 12 through 19]

According to applicants, "[p]hytase enzyme compositions are not recognized to reduce the levels of ribonucleic acid materials and associated minerals in vegetable protein materials since the most common phytases . . . do not degrade the ribonucleic acid structure." (Id., page 2, lines 26 through 29).

Applicants have attached several publications to their Appeal Brief and Reply Brief as support for this argument. For example, according to applicants, the Leach

publication (Appendix C of the Brief) teaches that "one skilled in the art would not expect phosphatases to degrade polymeric nucleotides such as ribonucleic acids" (Appeal Brief, page 13, first full paragraph). Also, the Cech patent (Appendix D of the Brief) "illustrates that one skilled in the art separately classifies RNA cleaving enzymes (endoribonucleases) from dephosphorylating enzymes such as acid phosphatase (dephosphorylases)" (*Id.*). According to applicants, the BASF publication (Exhibit A of the Reply Brief) and the Wong declaration (Exhibit B of the Reply Brief) further support this line of argument. See applicants' Reply Brief, pages 5 and 8.

Applicants argue that their claimed invention "is not inherently anticipated by the '343 patent since the '343 patent does not necessarily require the use of an acid phosphatase enzyme to produce a phytate-free or low-phytate soy protein, and, therefore, degradation of ribonucleic acids with an acid phosphatase enzyme cannot be a necessary consequence of, does not naturally flow from, and is not always present in the method disclosed in the '343 patent" (Appeal Brief, page 7, first full paragraph, emphasis added).

We disagree with that reasoning. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Additionally, even when processes "encompassed by the claims are not entirely old, the rule is applicable . . . to the extent that the claims and the prior art overlap." *Id.*

It appears to us that applicants have merely discovered and are claiming a new benefit of the method disclosed in the '343 patent where Finase is employed as the enzyme preparation. As stated by applicants:

The present invention resides in the discovery that acid phosphatase enzymes unexpectedly cleave ribonucleic acids . . . [a]lthough certain commercially available phytase enzyme preparations include acid phosphatases, it has not been previously recognized that acid phosphatases are useful for degrading ribonucleic acids, and that the concentration of ribonucleic acids in vegetable protein materials can be reduced by treatment with an acid phosphatase. [Specification, page 4, first full paragraph]

and

Applicants agree with the Examiner's statement that the reference clearly teaches use of an enzyme preparation that contains an acid phosphatase, and that such an enzyme preparation is utilized in an aqueous suspension of a soy protein material. Applicants would also agree that RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent. [Appeal Brief, page 8, second full paragraph, emphasis added].

We emphasize here that Finase, an enzyme preparation containing acid phosphatase, is particularly preferred for the purposes of carrying out the invention disclosed in the '343 patent. See the '343 patent, page 6, lines 26 and 27; and see comparative examples 2 through 5, pages 7 through 10. The cited prior art reference puts a person having ordinary skill in possession of the disclosed embodiment using Finase enzymes.³

³ Exhibit C attached to the Reply Brief is the Taylor declaration, filed under the provisions of 37 CFR § 1.132, executed June 17, 2003. In paragraph 5, declarant refers to the following statement in the Appeal Brief, page 8, second full paragraph: "Applicants would also agree that RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343

(continued...)

Applicants argue that “for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference” (Appeal Brief, bottom of page 6, citing Mehl/Biophile International Corp. v. Milgraum, 192 F.3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999)). Therefore, according to applicants, because “the ‘343 patent does not require the use of an acid phosphatase enzyme to degrade phytates, although such an enzyme may be used . . . degradation of RNA in a vegetable protein with an acid phosphatase is not always present and is not a necessary consequence of the ‘343 patent (Id., page 9, emphasis added). Applicants thus argue a “may” versus “must” distinction. According to applicants,

the reference teaches processes that may utilize an enzyme preparation that contains an acid phosphatase enzyme in a vegetable protein material, but does not teach that the enzyme preparation must contain an acid phosphatase enzyme — regardless of the exclusive use of FINASE® enzyme preparations in the comparative examples of the reference. [Reply Brief, page 3, first full paragraph].

Again, “the reference discloses that use of the FINASE® enzyme preparations is a preferred method of practicing the disclosed invention, but that the process of the reference is not limited to use of FINASE® enzymes and can utilize any phytate-degrading enzyme preparation containing one or more phytate-degrading enzymes”

³(...continued)

patent.” According to declarant, that statement “was made in light of knowledge provided by the invention;” it “was not directed to explain the knowledge of those skilled in the art at or before the invention of the present patent application.” It can be seen that paragraph 5 of the Taylor declaration is consistent with our determination that appellants have discovered and are claiming a new benefit of the method disclosed in the ‘343 patent where Finase is employed as the enzyme preparation.

(Id., page 4). Applicants argue that “[t]he cited reference, therefore, clearly did not intend to limit the disclosed method of reducing phytates and phytic acids to using only FINASE® enzyme preparations” (Id., page 5, first full paragraph). The argument lacks merit.

The '343 patent discloses the use of Finase enzymes as a particularly preferred embodiment. See the '343 patent, page 6, lines 26 and 27; and see comparative examples 2 through 5, pages 7 through 10. Again, it is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase; and applicants acknowledge that RNA would be degraded by using an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent (Appeal Brief, page 8, second full paragraph). In our judgment, a person having ordinary skill in the art, given the disclosure of the '343 patent and its preferred embodiment using Finase enzymes, would inevitably and necessarily degrade RNA in the manner recited in claim 79. That a person having ordinary skill may work within the broad disclosure of the '343 patent without using Finase, or that the '343 patent discloses non-preferred embodiments, does not detract from the examiner's position. The '343 patent clearly and unequivocally discloses the use of Finase, and puts a person having ordinary skill in possession of the embodiment using Finase. Admittedly, RNA is degraded when using Finase in the method of the '343 patent.

Enzyme Concentration

Applicants also argue that “the ‘343 patent does not inherently disclose that the acid phosphatase enzyme is present in the mixture of enzyme and vegetable protein material in an amount relative to the protein material of from about 0.1% to about 10% by weight of the protein material (dry).” (Appeal Brief, page 9, first full paragraph).

Applicants acknowledge that enzyme dosages in the ‘343 patent “are presented as phytate-degrading units/g [soy] flakes” (the ‘343 patent, page 8, line 2). Nonetheless, according to applicants, “an enzyme activity level is not equivalent to a specified amount or concentration of an enzyme—it merely discloses how active the enzyme is. By definition, enzyme activity is the amount of an enzyme preparation required to effect a defined amount of a specific reaction in a defined amount of time.” (*Id.*, page 10, first full paragraph). The argument lacks merit.

The ‘343 patent clearly and unequivocally discloses using Finase enzymes in an aqueous suspension of a soy protein material; and it is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase. The use of Finase is particularly preferred for the purposes of carrying out the invention disclosed in the ‘343 patent, and its use is illustrated in comparative examples 2 through 5, pages 7 through 10. The reference puts a person having ordinary skill in possession of the disclosed embodiment using Finase, and applicants acknowledge that RNA would be degraded by using an enzyme preparation containing acid phosphatase in the method of the ‘343 patent. It appears reasonable to

say, therefore, that the amount of enzyme preparation used in the '343 patent is the same or substantially the same as the amount recited in claim 79. On these facts, the burden of persuasion shifted to applicants to establish a difference between the amount of enzyme preparation recited in claim 79 and the amount disclosed in the prior art reference. This applicants have not done. Applicants have presented no objective evidence or data on this record to show that the amount of enzyme used in the prior art is distinguishable from the amount recited in claim 79. In fact, applicants agree that "RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent" (Appeal Brief, page 8, second full paragraph). Compare In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote and citations omitted].

Nor does the disclosure of a non-preferred embodiment in the '343 patent detract from the examiner's position.

